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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/697,615 | 10/29/2003 | Kenneth E. Trueba | 10010217-3 | 9627 |

22879 7590 01/09/2006

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT PAPER NUMBER

3731

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/697,615 | TRUEBA, KENNETH E. | |
| | Examiner | Art Unit | |
| | Michael G. Mendoza | 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-27, 30 and 32-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-27, 30 and 32-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-7, 10, 11, 13-16, 33, 36, 43, 45-47, 50-53, 56, and 57 have been considered but are moot in view of the new ground(s) of rejection. The Applicant has amended the claims to include the new limitations of "multiple replaceable fluid reservoirs", "simultaneously deliver", and "each of the multiple reservoirs configured to hold a different bioactive composition". The newly added limitations change the scope of the claim requiring new consideration and an updated search. A new ground(s) of rejection is made in view of Klimowicz et al. 6543443 and Behar et al. 5169029.

2. Applicant's arguments filed 26 October 2005 have been fully considered but they are not persuasive. The Applicant argues that the McKinnon does not teach that the inhaler itself has a keypad located thereon. The limitations of the claim states that a keypad or touch screen is mounted on an external surface of the body in communication with the controller. The base unit 12 of McKinnon is removably mounted on an external surface of the inhaler (mouthpiece unit). The limitation is met by the device of McKinnon.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

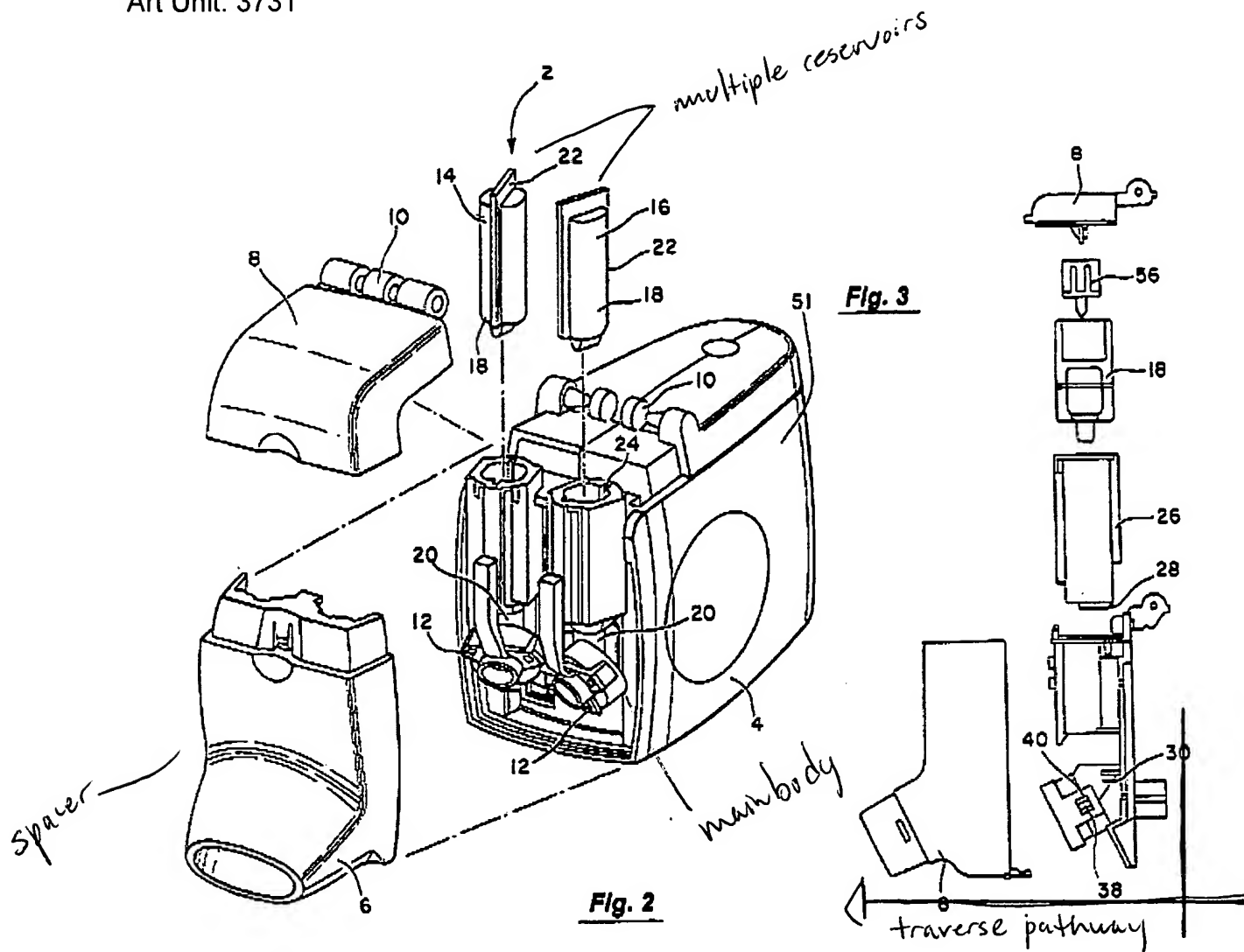
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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-7, 10, 12, 13, 15, 19-26, 30, 32-34, 43-46, 48-53, 56, and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Klimowicz et al. 6543443.

5. Klimowicz et al. teaches an applicator for delivering two or more different bioactive compositions comprising: an inkjet dispenser comprising an orifice 37, the inkjet dispenser further including a main body; multiple replaceable fluid reservoirs 14 and 16 configured to hold and to simultaneously deliver the bioactive compositions (col. 2, line 50-52); the replaceable fluid reservoirs at least partially insertable through the body, and each of the multiple reservoirs configured to hold a different bioactive composition; a body spacer 6; wherein the applicator is an inhaler; wherein the applicator is a pulmonary inhaler; wherein the inkjet dispenser is a piezoelectric droplet inkjet dispenser 48; wherein the spacer is external to the body; wherein the inkjet dispenser is adapted to dispense droplets of the bioactive composition sized for respiratory inhalation; wherein the inkjet dispenser is adapted to dispense droplets of the bioactive composition sized for delivery to bronchial airways; wherein the spacer is a mouthpiece spacer or a nasal spacer and the inkjet dispenser is disposed within the spacer; a programmable controller 51 adapted to control the inkjet dispenser; wherein the controller is programmed to deliver bioactive compositions from the applicator in response to clinical or physical information (col. 4, line 10 thru col. 5, line 20).

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-7, 10-16-19-27, 30, 32-36, and 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voges 5894841 in view of Behar et al. 5169029.

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8. Voges teaches an applicator for delivering a bioactive composition, comprising: an inkjet dispenser 14 comprising an orifice 15, the inkjet dispenser further including a main body (14 + 15); a replaceable fluid reservoir 10, the replaceable fluid reservoir at least partially insertable through the body (11 + 12); a body orifice spacer 5;

9. It should be noted that Voges fails to teach multiple replaceable fluid reservoirs configured to hold and to simultaneously deliver bioactive compositions, and each of the multiple reservoirs configured to hold a different bioactive composition.

10. Behar et al. teaches a common inhaler comprising multiple replaceable fluid reservoirs for administering medication from multiple aerosol containers (col. 2, lines 28-35). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inhaler of Voges to include the fluid reservoirs of Behar et al. for discharging medicaments intended to be prepared shortly before their use (col. 2, lines 44-47).

11. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use multiple reservoirs, since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

12. Voges/Behar teaches the applicator as above, wherein the applicator is an inhaler; wherein the applicator is a pulmonary inhaler; wherein the inkjet dispenser is a piezoelectric droplet inkjet dispenser; wherein the spacer is external to the body (figs. 1, 2, & 4); wherein the inkjet dispenser is adapted to dispense droplets of the bioactive composition sized for respiratory inhalation; wherein the inkjet dispenser is adapted to

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dispense droplets of the bioactive composition sized for delivery to bronchial airways (col. 3, line 62-col. 4, line 33); wherein the spacer is a mouthpiece spacer or a nasal spacer and the inkjet dispenser is disposed within the spacer (fig. 2); a fluid conduit extending between the fluid reservoir and the inkjet dispenser (fig. 2), the fluid conduit adapted to deliver the bioactive composition from the fluid reservoir to the inkjet dispenser, the fluid conduit extending at least partially through the spacer; wherein the spacer is adapted to change a delivery direction (fig. 4); wherein the inkjet dispenser is a thermal droplet inkjet dispenser (col. 3, line 62-col. 4, line 33); a programmable controller 16 adapted to control the inkjet dispenser; and wherein the programmable controller is a microprocessor (col. 6, lines 45-50).

13. Claims 17, 18, 37-42, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klimowicz et al. in view of McKinnon et al. 6190326.

14. Klimowicz et al. teaches the inhaler as in the above rejected claims. It should be noted that Klimowicz et al. fails to teach wherein the controller is programmable from a remote computer and the controller is programmable from a keypad mounted on an external surface.

15. McKinnon et al. teaches a common controller for accurately collecting information about a patient's respirator condition (col. 1 lines, 41-43). Therefore it would have been obvious to one of ordinary skill in the art to modify the controller of Klimowicz et al. to include the remote computer 18 and keypad 52 of McKinnon et al. to allow entry of the specifics of a treatment plan a physician (col. 5, lines 26-28).

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16. Claims 17, 18, and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voges in view of Behar et al. in further view of McKinnon et al. 6190326.

17. Voges/Behar teaches the inhaler as in the above rejected claims. It should be noted that Voges/Behar fails to teach wherein the controller is programmable from a remote computer and the controller is programmable from a keypad mounted on an external surface.

18. McKinnon et al. teaches a common controller for accurately collecting information about a patient's respirator condition (col. 1 lines, 41-43). Therefore it would have been obvious to one of ordinary skill in the art to modify the controller of Voges/Behar to include the remote computer 18 and keypad 52 of McKinnon et al. to allow entry of the specifics of a treatment plan a physician (col. 5, lines 26-28).

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contacts


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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PRIMARY EXAMINER